

K961928

SEP 16 1996

TO: Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FROM: Daniel J. Dyar, President

DATE: May 17, 1996 (Revised June 11, 1996)

SUBJECT: 510 K Summary

TRADE NAME: I.V. Extension with Stopcock.

COMMON NAME: I.V. Extension

CLASSIFICATION NAME: [880.5440] Intravascular Administration Set

**SUBSTANTIALLY
EQUIVALENT TO:**

Biomedix, Inc. claims substantial equivalence regarding this design of the I.V. Extension Line Assembly with Stopcock as follows:

Products currently on the market include:

Baxter PHARMASEAL K52 NOVEX Three-Way Stopcock with Extension Tube.
(Sterile, For Single Use Only, Capacity 2.3 mL, Length 50.8 cm. Blue Protector covers Male Adapter.)

Medex Extension Set - 12" Extension with "Y" Injection Site.

McGaw - G0719 I.V. Extension Set, Female and Needle Adapter, Vol. 3 mL., Length 21"
G0726 I.V. Extension Set with (2) Injection Sites, Vol. 6 mL., Length 33"
G0716 I.V. Extension Set with (2) Injection Sites with check valve and
flashtube., Vol. 6 mL., Length 34"

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510 K SUMMARY (CONTINUED)

DESIGN COMPARISONS:

COMPONENT	BIOMEDIX	BAXTER K52	MEDEX EXTENSION SET
Stopcock	All 3 ports include both threaded and / or slip luer connections.	(1) Port has removeable needle injection site. (2) remaining ports have slip luer conn. only.	(1) Y - Port for Sharps Devices.
Capacity	3.75 ml.	2.3 ml.	N/A
Tubing	.114 +/- .002" I.D.	.088-.090" I.D.	N/A
Connections	Choice of Needle or Blunt Cannula Y-Site with Male Slip Luer Connector.	Male Slip Luer Connector Only.	Male Slip Luer Connector Only.

The Biomedix design allows injection of solutions directly at the Patient I.V. Catheter. A slip-type clamp on the tubing portion of the I.V. Extension Line allows the line to be shut-off preventing backflow and/or dilution of administered fluids away from the patient.

DESCRIPTION:

The I.V. Extension Line Assembly with Stopcock is attached to the Primary I.V. to facilitate two advantages. One, is to add extra length between the I.V. Supply and the Patient. A second, is to provide additional supply ports for the administration of alternate solutions and special drugs that are administered intravenously. A four-way stopcock offers selection of the fluid types and sources. Biomedix is offering two models, one with a standard Needle-Type Injection Site at the Outlet and a second with a Blunt Cannula (Needleless) Type Injection Site at the outlet.

INTENDED USE:

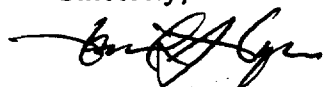
This product would be used by Nurses and Paramedics in prehospital, emergency room and field situations.

510 K SUMMARY (CONTINUED)

SUMMARY OF DEVICE COMPARISONS:

Basic constuction of both Biomedix and Competitive Products of this type are of commercially available components. Biomedix already employs a process and construction similiar to this in their existing Selec-3 Primary I.V. Set.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel J. Dyar", written over a horizontal line.

Daniel J. Dyar
President Biomedix, Inc.